

REMARKS

The present application relates to inbred maize plant and seed PH581. Claims 1-10 are pending in the present application. Claims 2, 7 and 9 have been amended. Applicants acknowledge the addition of claims 11 through 30. No new matter has been added by way of amendment. Applicants respectfully request consideration of the claims in view of the following remarks.

Detailed Action

A. Double Patenting

Applicants acknowledge the Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c) submitted on April 15, 2005 has obviated the double patenting rejection of record.

B. Claims

Applicants acknowledge the addition of claims 11 through 30. The new claims do not add new matter as there is support for the claims in the originally filed specification. Support for the specific items can be found within the specification for herbicide tolerance on pages 32-33; insect resistance and resistance to bacterial, fungal, nematode or viral disease on pages 29-32; yield enhancement on page 22; waxy starch and improved nutritional quality on page 22; male sterility on pages 2-3; restoration of male fertility on pages 2-3 and 0-5 generations on pages 3-4. No new matter has been added. Applicants respectfully request consideration of the claims in view of the following remarks.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Written description regarding Claims 1-10

Claims 1-10 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states the rejection is repeated for the reasons of record set forth in the Office Action of December 17, 2004. The Examiner states " ... each hybrid would have a completely different set of morphological traits, influenced by the genetic makeup of the second inbred parent". The Examiner further states "that no correlation

has been demonstrated between structure (gene sequence of one parent inbred) and function (the morphological complement of each divergent F1 hybrid descended from a different second parent)." (Office Action, p. 2-3).

Applicants respectfully traverse this rejection. Applicants reiterate that the written description requirement has been satisfied by the actual reduction to practice of F1 hybrid seed/plant produced by inbred maize line PH581, by the deposit of a common identifying structural feature of the claimed F1 hybrid seed and plants and by the morphological description of Table 1 of the specification. (See specification, p. 19-21).

In order to satisfy the written description requirement, the Applicants "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). In essence, "the description must clearly allow persons of ordinary skill in the art to recognize that [the Applicant] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2d 1614, 1618 (Fed. Cir. 1989). An Applicant's claims are described where they set forth and define "structural features commonly possessed by members of the genus that distinguish them from others." *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406 (emphasis added). For inventions similar to the present Applicants, "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The Board of Patent Appeals & Interferences has also confirmed the sufficiency of a deposit for seed and plants in the case of *Ex Parte C*, 1992 WL 515817 p. * 5, 27 U.S.P.Q.2d 1492, 1496 (B.P.A.I. 1992), where it stated that "[t]he claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention."

Further, in order to satisfy the written description requirement, Applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art". *Regents of University of California v. Eli Lilly*, 119 F.3d 1559, 1569, 43 U.S.P.Q.2d 1398, 1406

(Fed. Cir. 1997) (citing as analogous argument *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q.2d 214, 218 (Cust. & Pat. App. 1976)). Consistent with this principal, the Board of Patent Appeals & Interferences, in a case involving the written description requirement as applied to seed and plants, stated "[i]f in making the latter comment the examiner is requiring appellants to have reduced to practice each possible plant within the scope of the claims, such a position is legally incorrect. The specification need only teach one skilled in the art how to make and use the claimed invention. How the specification does so, whether by way of the written word or actual examples, is of no moment." *Ex parte Gerardu C.M. Bentvelsen et al.*, 2001 WL 1197757, p. *2 (B.P.A.I. 2001). In addition, a claim to the genus of F1 hybrids made with a patented inbred was expressly acknowledged by the U.S. Supreme Court when it stated that "...a utility patent on an inbred plant line protects the line *as well as all hybrids* produced by crossing that inbred with another plant line." *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143; 122 S.Ct. 593, 604; 60 U.S.P.Q.2d 1865, 1873 (2001) (emphasis added). Therefore, Applicants submit that based on the data provided in the specification and the above the function of the hybrid has been correlated to the set of chromosomes originating from the deposited PH581 seed.

In addition to description by structure, the written description requirement may be satisfied by disclosing functional characteristics where there is a correlation between structure and function. The Federal Circuit has stated that the written description requirement may be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, *functional characteristics when coupled with a known or disclosed correlation between function and structure*, or some combination of such characteristics." *Enzo Biochem, Inc.*, 323 F.3d at 964, 63 U.S.P.Q.2d at 1613 (quoting and adopting the USPTO's Written Description Guidelines, 66 Fed. Reg. 1106, No. 4 (2001)). As stated *supra*, Applicants have disclosed sufficiently detailed, relevant identifying characteristics in the Tables provided and therefore has in fact complied with the requirement of written description.

Further, the primary utility of an inbred is in the hybrid it will produce, and Applicants have provided ample description of the hybrids produced by PH581 in the application as filed. (Specification, p. 1, ll. 29-34; pp. 19-21, Table 1; pp. 40-42, Table 3A-3C; pp. 43-49, Tables 4A-4D). As stated in the MPEP, §2163(II)(A)(3)(a)(ii), the written description requirement for a

genus may be satisfied by sufficiently describing a representative number of species actually reduced to practice. These hybrids are thus representative of the hybrids produced using PH581 as a parent. This is sufficient to meet the written description requirement. *See Ex parte Garing*, p. 18 (B.P.A.I. 2005) (stating "[i]n addition, the examiner appears to recognize . . . that appellant's specification describes an exemplary hybrid wherein one parent was a plant of the corn variety [inbred number]. . . Accordingly, it is unclear to this merits panel what additional description is necessary.").

Applicants submit that in accordance with the *Eli Lilly* standard recited by the Examiner, the genus of F1 hybrids encompassed by Applicants claims 1-10 and new claims 11-30 are described with precise definition in a manner which provides structure sufficient to distinguish an F1 hybrid made with PH581 from an F1 hybrid not made with PH581. This is because cells and/or chromosomes of inbred line PH581 provide an identifying structural feature possessed by all members of the claimed genus. (For example, *see* U.S. Patent No. 6,717,037, Table A, column 12, line 4 through column 13, line 61). In addition, new claims 11-30 were added to further characterize the claimed invention. Therefore, since Applicants have deposited the seed of inbred maize PH581 thereby allowing one skilled in the art to identify the F1 hybrids in relation to the structural feature of the claimed invention, the written description requirement of 35 U.S.C. § 112, first paragraph has been met.

The legal standards for the written description requirement are discussed *supra*, and the written description requirement does not mandate a description via morphological and physiological characteristics. Applicants refer the Examiner to the case of *Ex Parte Tanksley*, 37 USPQ2d. 1382. In that case, the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement...that the appellants amend their claims in a specified manner...We find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a § 112 second paragraph rejection, held that "[i]n our judgement, a patent applicant is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. § 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the prior art.

Stated another way, a patent applicant must comply with 35 U.S.C. § 112, second paragraph, but just how the applicant does so, within reason, is within applicant's discretion." *Id.* at 1386.

One skilled in the art would thus recognize that Applicants were in possession of F1 hybrid seed and plants produced from line PH581 as of the filing date of the application. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

B. Enablement regarding Claims 1-10

Claims 1-10 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner asserts that the claims(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Examiner maintains "that each reference teaches the general unpredictability inherent in corn breeding". (Office Action, p. 4).

Applicants respectfully traverse. Inbred maize lines are primarily used to produce F1 hybrid seed and plants. The claimed F1 hybrid seed is routinely and easily produced by crossing a plant from inbred maize line PH581 with a plant from another inbred maize line. Applicants have described how to produce an F1 hybrid from inbred maize line PH581. (Specification, p. 3, l. 17-p. 4, l. 28). Applicants have also made a deposit of inbred PH581 that fully enables others to obtain the inbred seed needed to make the claimed F1 hybrids.

Applicants reiterate the arguments regarding the references cited by the Examiner as previously presented in the Amendment of April 18, 2005. Applicants assert the references relate to segregating populations of seed (Kevern), selection within the segregating populations of seed (Carlone), comparison of synthetic populations (Stuber *et al.*), and the making of all possible crosses including F2, 3-way and backcrosses (Melchinger) to produce a population of seed. In contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. An F1 hybrid as claimed is not a genetically mixed population, but rather is highly homogeneous and reproducible because it is made from the highly homogeneous and reproducible inbred maize line PH581. (Specification, p. 16, lines 17-18). Therefore, the Examiner's assertions are respectfully incorrect because in the present invention the genomic structure of PH581 is shared by the claimed genus of hybrids, due to the highly

homogenous nature of the PH581 genetic complement. These are known facts to one of ordinary skill in the art of inbred maize lines and are sufficient to provide the distinguishing characteristics necessary to comply with 35 U.S.C. § 112, first paragraph. The Applicants have thus provided "distinguishing characteristics" of the claimed genus. As explained above, these specific identifying characteristics are the cells and/or chromosomes of PH581 described in the deposit of the present application and present in the claimed F1 hybrid genus. The cells and/or chromosomes are present in the genus of F1 hybrids made with PH581 and absent in the genus of F1 hybrids not made with PH581. To require Applicants to further describe aspects of the claimed invention that are not the point of patentability of the genus extends the written description requirement beyond the legal standard. Thus, Applicants respectfully assert the arguments set forth by the Examiner do not apply to the presently claimed invention.

Applicants have described how to produce an F1 hybrid from inbred maize line PH581. In addition, one skilled in the art of corn breeding would know that the F1 plants and seed of claims 1-10 can routinely and easily be produced by crossing PH581 with another inbred maize line. Accordingly, Applicants submit that claims 1-10 are fully enabled and have fully satisfied the legal standards for enablement.

Summary

Applicants acknowledge that claims 1-10 are deemed free of the prior art. The Examiner states the prior art fails to teach or fairly suggest inbred maize plant PH581, or method of using it. This clearly indicates that maize inbred line PH581 as a whole is considered to be distinguishable from the prior art for the purposes of novelty and non-obviousness.

Conclusion

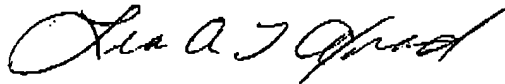
In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

This Amendment accompanies a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of \$790.00 per the attached RCE Transmittal. Please also charge Deposit Account No. 26-0084 the amount of \$700.00 for 10 additional claims

over 20 (\$50 each) and 1 additional independent claim over 3 (\$200 each). No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



LILA A. T. AKRAD, Reg. No. 52,550
MCKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 27142

- LATA /bj -

Attorneys of Record